

**REMARKS**

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the specification and claims and the following remarks.

***Status of the Claims***

In the present Amendment, claims 1-4 and 9 have been amended and claims 10-22 have been added. This makes claims 1-22 as pending in the present application.

No new matter has been added by way of these amendments because each amendment is supported by the present specification. For example, the subject matter of claim 2 has been incorporated into claim 1. Regarding the amendment to claim 2 and new claim 21, Applicants note the specification at page 6, lines 15-17 or paragraph [0015]. Claim 3 has been amended into independent form. Also, the amendment to claim 9 has support in the specification at paragraph [0054]. New claims 12-21 which depend on claim 3 are drawn to preferred embodiments of the present invention and have been added for consideration. Support for new claims 12-18 is found in, for example, original claims 2 and 4-9. Support for new claims 10, 11, 19 and 20 is found in the present specification at paragraph [0023]. Finally, new claim 22 has support in paragraphs [0054]-[0055] of the specification.

No new matter has been added with the change to Table 3 of the specification, as "12-hydroxystearic acid" was misspelled.

Based upon the above considerations, entry of the present amendment is respectfully requested.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

***Issues under 35 U.S.C. § 112, First Paragraph***

Claim 9 stands rejected under 35 U.S.C. § 112, first paragraph for asserted lack of written description (see pages 2-3 of the Office Action). Applicants respectfully traverse and reconsideration is based on the following remarks.

Applicants respectfully refer the Examiner to claim 9 as shown herein, wherein it is believed that the present amendments sufficiently address this rejection.

***Issues under 35 U.S.C. §§ 102 and 103(a)***

Claims 1, 2 and 5 stand rejected under 35 U.S.C. § 102(b) as being anticipated by **Janeuszewski '319** (U.S. Patent No. 4,159,319) (Office Action at pages 3-5).

Also, claims 4, 6 and 7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over **Janeuszewski '319** as applied to claims 1, 2 and 5 (see pages 5-6 of the Office Action).

Further, claims 8 and 9 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over **Janeuszewski '319** in further view of **Ibsen '386** (U.S. Published Applic. No. 2002/0006386) (see pages 6-7 of the Office Action).

Applicants respectfully traverse and reconsideration is based on the following remarks.

The Present Invention and Its Advantages

An object of the present invention to provide a nonaqueous gel composition for tooth whitening and a tooth whitening set, which change the optical properties of the enamel without using any peroxide, thereby making teeth apparently look white while permitting teeth to restore their original color in the presence of water and which keep the whitening effect over a long period of time.

The present inventors carried out extensive investigations on the method for whitening teeth with a composition containing a tooth whitening ingredient which penetrates into the enamel of the tooth for replacement of water therein, thereby changing the optical properties (such as refractive index and reflectivity) of the enamel without chemical reactions (such as bleaching) so that the treated teeth apparently look white. As the result, they found that it is possible to protect the tooth whitening ingredient, which has once penetrated into the enamel, from leaching out of the enamel by incorporation with a substance (such as C<sub>14-22</sub> higher fatty acids and/or acrylic acid copolymers) which dissolves in the tooth whitening ingredient and is precipitated by an aqueous solution of calcium chloride, which is selected from among C<sub>14-22</sub> higher fatty acids and/or acrylic acid copolymers.

Distinctions over Januszewski '316, the modification thereof, and the further combination with Ibsen '386

The Januszewski '316 reference discloses a nonaqueous composition that has propylene glycol as essential ingredients and high fatty acids and hydroxypropylcellulose as gel agents. However, Januszewski '316 fails to disclose the use of the ingredient (A) which is selected from

isopropanol, butanol, ethylene glycol, polyethylene glycol (with an average molecular weight of 190 to 630), diethylene glycol, butylene glycol, and glycerin as instantly claimed. Applicants note claim 1 as amended herein. In this regard, the rejection under § 102(b) has been instantly overcome as there is no disclosure of all claimed features. *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949 (Fed. Cir. 1990) (citing *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)).

Regarding the rejections of claims 4, 6 and 7 under § 103(a), and as the M.P.E.P. directs, all claim limitations must be considered in view of the cited prior art in order to establish a *prima facie* case of obviousness. See MPEP § 2143.03. Also, if an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *see also* MPEP § 2143.03. Here, as mentioned above, Januszewski '316 fails to disclose the instantly claimed ingredient (A). Furthermore, Januszewski '316 fails to guide one of ordinary skill in the art to the features of the present invention, as the reference also lacks disclosure of the above-mentioned effects by incorporating ingredient (B) in the presently claimed nonaqueous gel composition. Thus, Januszewski '316 fails to disclose all features and advantages of the present invention.

M.P.E.P. § 2143 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors of: determining the scope and content of the prior art; ascertaining the differences between the prior art and the claims that are at issue; resolving the level of ordinary skill in the pertinent art; and evaluating any evidence of secondary

considerations (e.g., commercial success; unexpected results). 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). Second, the Examiner has to provide some rationale for determining obviousness, wherein M.P.E.P. § 2143 set forth some rationales that were set established in the recent decision of *KSR International Co. v Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007). Here, the Examiner has not appropriately resolved the *Graham* factors, including ascertaining the differences between the prior art and the claims that are at issue (e.g., Januszewski '316 fails to disclose the instantly claimed ingredient (A)).

The status of pending claim 3 is respectfully requested, as it appears that this claim is allowable.

Regarding claim 3, Januszewski '316 does disclose the use of higher fatty acid as a particulate carrier material to solve flavorings. However, Januszewski '316 fails to disclose the use of the ingredient (B) which is selected from among C<sub>14-22</sub> higher fatty acids and/or acrylic acid copolymers, and the above-mentioned effects by incorporation with the tooth whitening ingredient in the present inventive nonaqueous gel composition. Thus, the features of pending, independent claim 3 are also not disclosed in Januszewski '316.

Furthermore, the superiority of the present invention of independent claim 3 is evident from the results of Comparison No. 3 which uses lauric acid (C<sub>12</sub> higher fatty acid) instead of the instantly claimed ingredient (B). In this regard, *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), has provided the controlling framework for an obviousness analysis, wherein a proper analysis under § 103(a) requires consideration of the four *Graham* factors. One such factor includes the evaluation of any evidence of secondary considerations (e.g., commercial success; unexpected results). 383 U.S. at 17, 148 USPQ at 467. Applicants

respectfully submit that the present invention has achieved unexpected results, whereby such results rebut any asserted *prima facie* case of obviousness.

Here, Comparative Example 3 (shown in Table 4 at page 26) achieves the inferior result of “X” for endurance of tooth whitening effect. Applicants note, for example, Inventive Example 6 having the same amounts of 1,3-dibutylene glycol and hydroxylpropyl cellulose (but incorporating 12-hydroxystearic acid). The Inventive Examples are achieved superior endurance of whitening effects. The comparative showing need not compare the claimed invention with all of the cited prior art, but only with the closest prior art. *See* M.P.E.P. §§ 716.02(b) and 716.02(e).

Applicants further submit that this rejection under § 103(a) is overcome because evidence of unexpected results is in the present specification and it is improper to not consider such evidence of patentability for the present invention. *See In re Soni*, 54 F.3d 746, 34 U.S.P.Q.2d 1684 (Fed. Cir. 1995) (error not to consider evidence in the specification); M.P.E.P. § 2144.08(II)(B).

Accordingly, Januszewski ‘316 fails to disclose and teach the all features and advantages of the present invention and the rejection under § 102(b) has been overcome. Also, as mentioned above, since the amended claim 1 and original claim 5, and also the independent claim 3 are all patentable over Januszewski, the other claims of 4-9 are patentable over the modification of Januszewski ‘316 or with the further combination with Ibsen ‘386. Also, a proper weighing of the *Graham* factors resides in Applicants’ favor of patentability.

*Application No. 10/584,192*  
*Art Unit 1612*  
*Reply to Office Action of August 7, 2008*

*Docket No.: 0171-1287PUS1*

***Conclusion***

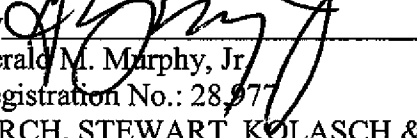
A full and complete response has been made to all issues as cited in the Office Action. Applicants have taken substantial steps in efforts to advance prosecution of the present application. Thus, Applicants respectfully request that a timely Notice of Allowance issue for the present case.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T. Perez (Reg. No. 48,501) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

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